



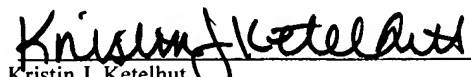
DOCKET NO.: C1037.70039US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Davis et al.  
Serial No.: 10/816,220  
Confirmation No.: 8632  
Filed: April 1, 2004  
For: IMMUNOSTIMULATORY NUCLEIC ACID OIL-IN-WATER  
FORMULATIONS AND RELATED METHODS OF USE  
Examiner: Not Yet Assigned  
Art Unit: 1653

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 25 day of March, 2005.

  
Kristin J. Ketelhut

MAIL STOP AMENDMENT

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*Davis et al., Applicant*

By:



Maria A. Trevisan, Reg. No.: 48,207  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: C1037.70039US01  
Date: March 25, 2005  
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DOCKET NO.: C1037.70039US01

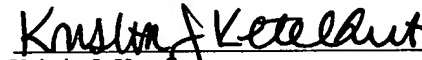
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Davis et al.  
Serial No.: 10/816,220  
Confirmation No.: 8632  
Filed: April 1, 2004  
For: IMMUNOSTIMULATORY NUCLEIC ACID OIL-IN-  
WATER FORMULATIONS AND RELATED METHODS  
OF USE  
Examiner: Not Yet Assigned  
Art Unit: 1653

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Kristin J. Ketelhut

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**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
*C1037.70048US00	10/644,052	August 19, 2003	Jurk et al.
*C1037.70049US00	10/643,141	August 18, 2003	Hutcherson et al.
*C1037.70050US01	10/952,254	September 27, 2004	Uhlmann et al.
*C1037.70052US00	10/668,050	September 22, 2003	Bratzler et al.
*C1037.70053US01	11/061,140	February 18, 2005	Lipford et al.
*C1037.70054US01	10/973,927	October 25, 2004	Lipford et al.
C1039.70020US00	09/337,584	June 21, 1999	Krieg et al.
*C1039.70020US01	10/921,086	August 18, 2004	Krieg et al.
C1039.70022US00	09/337,893	June 21, 1999	Krieg
C1039.70035US00	09/669,187	September 25, 2000	Krieg et al.
C1039.70041US00	09/655,319	September 5, 2000	Krieg et al.
C1039.70042US00	09/630,319	July 31, 2000	Krieg et al.
C1039.70043US00	09/629,477	July 31, 2000	Krieg et al.
C1039.70044US00	09/672,126	September 27, 2000	Hartmann et al.
*C1039.70044US01	11/056,463	February 11, 2005	Hartmann et al.
*C1039.70048US03	10/831,647	April 23, 2004	Krieg et al.
*C1039.70048US06	10/884,852	July 2, 2004	Krieg et al.
*C1039.70048US11	10/928,762	August 26, 2004	Krieg et al.
*C1039.70048US12	10/956,745	October 1, 2004	Krieg et al.
*C1039.70048US13	10/956,494	October 1, 2004	Krieg et al.

\*a copy of this reference is not provided as the Office hereby waives the requirement under 37 CFR 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application filed after June 30, 2003 and for applications filed before June 30, 2003, or that entered the national stage before June 30, 2003, if they are scanned to Image File Wrapper system and are available on Private PAIR.

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<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
*C1039.70048US14	10/972,301	October 22, 2004	Krieg et al.
*C1039.70048US15	10/987,146	November 12, 2004	Krieg et al.
*C1039.70048US16	11/031,460	January 7, 2005	Krieg et al.
*C1039.70048US17	11/036,527	January 14, 2005	Krieg et al.
*C1039.70048US18	11/067,587	February 25, 2005	Krieg et al.
C1039.70062US00	10/187,489	July 2, 2002	Krieg et al.
C1039.70070US00	10/382,822	March 6, 2003	Krieg et al.
C1039.70071US00	10/435,656	May 9, 2003	Krieg et al.
*C1039.70075US00	10/613,916	July 3, 2003	Krieg et al.
*C1039.70077US00	10/619,279	July 14, 2003	Krieg
*C1039.70079US00	10/627,413	July 25, 2003	Krieg et al.
*C1039.70083US11	11/067,516	February 25, 2005	Krieg et al.
C1040.70006US00	09/316,199	May 21, 1999	McCluskie et al.
C1041.70002US00	09/241,653	February 2, 1999	Wagner et al.
C1041.70005US00	09/355,254	February 22, 2000	Wagner et al.
*C1041.70005US01	10/811,226	March 26, 2004	Wagner et al.
C1041.70010US00	09/786,436	March 2, 2001	Wagner et al.
*C1041.70016US01	10/884,372	July 2, 2004	Bauer et al.
*C1041.70034US01	10/978,283	October 29, 2004	Uhlmann et al.
*C1041.70036US01	10/872,196	June 18, 2004	Lipford et al.
*C1041.70040US00	10/666,844	September 19, 2003	Lipford et al.
*C1041.70041US01	10/982,193	November 5, 2004	Bauer et al.
*C1041.70043US01	10/977,560	October 29, 2004	Jurk et al.

\*a copy of this reference is not provided as the Office hereby waives the requirement under 37 CFR 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application filed after June 30, 2003 and for applications filed before June 30, 2003, or that entered the national stage before June 30, 2003, if they are scanned to Image File Wrapper system and are available on Private PAIR.

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The Applicant would like to bring to the Examiner's attention the enclosed search report or other communication from a corresponding International Application.

<u>Docket No.</u>	<u>Serial No.</u>	<u>Mailing Date</u>	<u>Type of Communication(s)</u>
C1037.70039WO00	PCT/IB2004/001371	21 October 2004	International Search Report
C1037.70039WO00	PCT/IB2004/001371	21 October 2004	Written Opinion

### PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

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Conf. No.: 8632

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Art Unit: 1653

An early and favorable action is hereby requested.

Respectfully submitted,  
*Davis et al., Applicant*

By:



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Maria A. Trevisan, Reg. No. 48,207  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: C1037.70039US01  
Date: March 25, 2005  
**xNDDx**

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Sheet 1 of 23

APPLICATION NO.: 10/816,220

ATTY. DOCKET NO.: C1037.70039US01

FILING DATE: April 1, 2004

CONFIRMATION NO.: 8632

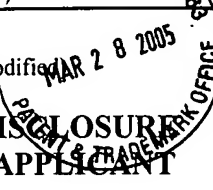
APPLICANT: Davis et al.

GROUP ART UNIT: 1653

EXAMINER: Not Yet Assigned

## U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	3,906,092		Hilleman et al.	09-16-1975
	A2	4,452,775		Kent	06-05-1984
	A3	4,544,559		Gil et al.	10-01-1985
	A4	4,994,442		Gil et al.	02-19-1991
	A5	5,023,243		Tullis	06-11-1991
	A6	5,066,500		Gil et al.	11-19-1991
	A7	5,075,109		Tice et al.	12-24-1991
	A8	5,087,617		Smith	02-11-1992
	A9	5,093,318		Goodman et al.	03-03-1992
	A10	5,112,605		Jardieu et al.	05-12-1992
	A11	5,248,670		Draper et al.	09-28-1993
	A12	5,457,189		Crooke et al.	10-10-1995
	A13	5,514,577		Draper et al.	05-07-1996
	A14	5,543,152		Webb et al.	08-06-1996
	A15	5,567,604		Rando et al.	10-22-1996
	A16	5,595,756		Bally et al.	01-21-1997
	A17	5,663,153		Hutcherson et al.	09-02-1997
	A18	5,679,397		Kuroda et al.	10-21-1997
	A19	5,684,147		Agrawal et al.	11-04-1997
	A20	5,705,385		Bally et al.	01-06-1998
	A21	5,723,335		Hutcherson et al.	03-03-1998
	A22	5,753,613		Ansell et al.	05-19-1998
	A23	5,756,097		Landucci et al.	05-26-1998
	A24	5,766,920		Babbitt et al.	06-16-1998
	A25	5,780,448		Davis	
	A26	5,785,992		Ansell et al.	07-28-1998
	A27	5,786,189		Locht et al.	07-28-1998
	A28	5,804,566		Carson et al.	09-08-1998
	A29	5,814,335		Webb et al.	09-29-1998
	A30	5,837,243		Deo et al.	11-17-1998
	A31	5,849,719		Carson et al.	
	A32	5,908,620		Tu et al.	06-01-1999
	A33	5,932,556		Tam	08-03-1999
	A34	5,955,059		Gilchrest et al.	09-21-1999
	A35	5,965,542		Wasan et al.	10-12-1999
	A36	5,976,567		Wheeler et al.	11-02-1999
	A37	5,981,501		Wheeler et al.	11-09-1999



<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		APPLICATION NO.: 10/816,220		ATTY. DOCKET NO.: C1037.70039US01		
		FILING DATE: April 1, 2004		CONFIRMATION NO.: 8632		
		APPLICANT: <u>Davis et al.</u>				
		GROUP ART UNIT: 1653		EXAMINER: Not Yet Assigned		
Sheet	2	of	23			

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A38	5,994,315		Nyce et al.	11-30-1999
	A39	6,004,534		Langer et al.	12-21-1999
	A40	6,013,639		Peyman et al.	01-11-2000
	A41	6,025,339		Nyce et al.	02-15-2000
	A42	6,027,726		Ansell	02-22-2000
	A43	6,030,955		Stein et al.	02-29-2000
	A44	6,040,296		Nyce et al.	03-21-2000
	A45	6,042,838		Briles et al.	03-28-2000
	A46	6,086,898		DeKruyff et al.	07-11-2000
	A47	6,090,791		Sato et al.	07-18-2000
	A48	6,110,745		Zhang et al.	08-29-2000
	A49	6,184,369	B1	Rando et al.	02-06-2001
	A50	6,191,257	B1	Ledley et al.	02-20-2001
	A51	6,194,388	B1	Krieg et al.	02-27-2001
	A52	6,207,646	B1	Krieg et al.	03-27-2001
	A53	6,210,663	B1	Ertl	04-03-2001
	A54	6,214,806	B1	Krieg et al.	04-10-2001
	A55	6,218,371	B1	Krieg et al.	04-17-2001
	A56	6,225,292	B1	Raz et al.	05-01-2001
	A57	6,239,116	B1	Krieg et al.	05-29-2001
	A58	6,339,068	B1	Krieg et al.	01-15-2002
	A59	6,406,705	B1	Davis et al.	06-18-2002
	A60	6,426,336	B1	Carson et al.	
	A61	6,429,199	B1	Krieg et al.	08-06-2002
	A62	6,498,147	B1	Nerenberg et al.	12-24-2002
	A63	6,498,148	B1	Raz	12-24-2002
	A64	6,503,533	B1	Korba et al.	01-07-2003
	A65	6,514,948	B1	Raz et al.	02-04-2003
	A66	6,534,062	B1	Raz et al.	03-18-2003
	A67	6,544,518	B1	Friede et al.	04-08-2003
	A68	6,552,006	B2	Raz et al.	04-22-2003
	A69	6,562,798	B1	Schwartz	05-13-2003
	A70	6,589,940	B1	Raz et al.	07-08-2003
	A71	6,610,308	B1	Haensler	08-26-2003
	A72	6,610,661	B1	Carson et al.	08-26-2003
	A73	6,630,455	B1	Mitchell	10-07-2003
	A74	6,653,292	B1	Krieg et al.	11-25-2003



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

APPLICATION NO.: 10/816,220

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CONFIRMATION NO.: 8632

APPLICANT: Davis et al.

GROUP ART UNIT: 1653

EXAMINER: Not Yet Assigned

Sheet 3 of 23

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A75	6,693,086	B1	Dow et al.	02-17-2004
	A76	6,727,230	B1	Hutcherson et al.	04-27-2004
	A77	6,737,066	B1	Moss	05-18-2004
	A78	6,787,524	B2	Chang et al.	09-07-2004
	A79	6,821,957	B1	Davis et al.	11-23-2004
	A80	2001-0034330	A1	Kensil	10-25-2001
	A81	2001-0036462	A1	Fong et al.	11-01-2001
	A82	2001-0041681	A1	Phillips et al.	11-15-2001
	A83	2001-0044416	A1	McCluskie et al.	11-22-2001
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	A86	2002-0028784	A1	Van Nest et al.	03-07-2002
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	A88	2002-0064515	A1	Krieg et al.	05-30-2002
	A89	2002-0086839	A1	Raz et al.	07-04-2002
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	A91	2002-0098199	A1	Van Nest et al.	07-25-2002
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	A94	2002-0142978	A1	Raz et al.	10-03-2002
	A95	2002-0156033	A1	Bratzler et al.	10-24-2002
	A96	2002-0164341	A1	Davis et al.	11-07-2002
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	A99	2003-0022852	A1	Van Nest et al.	01-30-2003
	A100	2003-0026782	A1	Krieg et al.	02-06-2003
	A101	2003-0026801	A1	Weiner et al.	02-06-2003
	A102	2003-0050261	A1	Krieg et al.	03-13-2003
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	A107	2003-0072762	A1	Van de Winkel et al.	04-17-2003
	A108	2003-0078223	A1	Raz et al.	04-24-2003
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

APPLICATION NO.: 10/816,220

ATTY. DOCKET NO.: C1037.70039US01

FILING DATE: April 1, 2004

CONFIRMATION NO.: 8632

APPLICANT: Davis et al.

GROUP ART UNIT: 1653

EXAMINER: Not Yet Assigned

Sheet 4 of 23

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A112	2003-0100527	A1	Krieg et al.	05-29-2003
	A113	2003-0104044	A1	Semple et al.	06-05-2003
	A114	2003-0104523	A1	Bauer et al.	06-05-2003
	A115	2003-0119773	A1	Raz et al.	06-26-2003
	A116	2003-0119774	A1	Foldvari et al.	06-26-2003
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	A142	2004-0006034	A1	Raz et al.	01-08-2004
	A143	2004-0009942	A1	Van Nest et al.	01-15-2004
	A144	2004-0009944	A1	Tam et al.	01-15-2004
	A145	2004-0009949	A1	Krieg	01-15-2004
	A146	2004-0030118	A1	Wagner et al.	02-12-2004
	A147	2004-0053880	A1	Krieg	03-18-2004
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

APPLICATION NO.: 10/816,220

ATTY. DOCKET NO.: C1037.70039US01

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GROUP ART UNIT: 1653

EXAMINER: Not Yet Assigned

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Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A149	2004-0067905	A1	Krieg	04-08-2004
	A150	2004-0087534	A1	Krieg et al.	05-06-2004
	A151	2004-0087538	A1	Krieg et al.	05-06-2004
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				FILING DATE: April 1, 2004		CONFIRMATION NO.: 8632	
				APPLICANT: Davis et al.			
				GROUP ART UNIT: 1653		EXAMINER: Not Yet Assigned	
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STATEMENT BY APPLICANT**

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CONFIRMATION NO.: 8632

APPLICANT: Davis et al.

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FORM PTO-1449/A and B (Modified)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/816,220	ATTY. DOCKET NO.: C1037.70039US01
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Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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